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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,380	07/24/2003	Ali Banan	88530	9783

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WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,380	BANAN ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (claims 17-32) in the reply filed on 7/24/06 is acknowledged.

Amendment Entry

2. In the response filed on 24 July 2006 claims 1-16 were cancelled. Currently claims 17-32 are pending and under consideration.

Priority

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending applications (10/263,207 filed 10/2/02), specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The specification should include the status of application number 10/263,207, "now abandoned". Please update the first line of the specification.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Please see the cited references throughout the disclosure.

5. The information disclosure statement filed 21 August 2003 has been considered as to the merits prior to a First Action.

Oath/Declaration

6. A new oath or declaration is required because the date has not been entered for the signatures of inventors Banan and Keshavarzian. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 17 and 32 the use of the term "in excess of experimental error" is vague and indefinite. It is not clear what Applicant intends by "experimental error" and/or how such error can be evaluated/measured/eliminated in the recited method. The term is not defined by the specification or the claims. Therefore, as recited the meets and bounds of the claim cannot be determined. It is suggested that the wording be eliminated in order to obviate this rejection. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 17, 18, 27, 28, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only).

Robinson et al. disclose a method of detecting free radical meditated oxidation via the formation of protein carbonyl groups. Protein samples prepared from tissue samples and cell cultures were slot blotted onto polyvinylidene difluoride membranes. The bound proteins were treated with 2, 4, dinitrophenylhydrazine (DNPH) and subsequently evaluated by chemiluminescent X-ray film for double antibody complex formation. See abstract. The unknown protein samples and BSA standards were concentrated to approximately 50 μg/mL (predetermined amount of protein). See page 50 2nd column 2nd paragraph-sample preparation.

The first antibody or primary antibody was an anti-dinitrophenyl-KLH rabbit IgG and the second antibody was a peroxidase conjugated $(Fab')_2$ fragment anti-rabbit IgG. See page 46 1st column-Chemicals. This procedure was specific and highly sensitive for the determination of carbonyl content in purified and in crude mixtures of proteins. See page 57 1st column 2nd paragraph.

Robinson et al. differ from the instant invention in not specifically teaching the utility of an anti-nitrotyrosine antibody in oxidative stress analyses.

However, Ischiropoulos et al. teach procedures to measure oxidative tissue injury associated with decreased pulmonary flow. Specifically, ischemic-reperfused lungs were used to measure the contribution or nitric oxide and peroxynitrite in tissue injury. The nitrotyrosine concentration increased in reperfused/ischemia lungs and specific binding of an anti-nitrotyrosine antibody was seen. See abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ an anti-nitrotyrosine antibody as taught by Ischiropoulos et al. in the oxidative procedure of Robinson et al. because Ischiropoulos et al. taught that nitrotyrosine concentrations increased in reperfused/ischemia lungs and specific binding of an anti-nitrotyrosine antibody was seen. See Ischiropoulos et al. - abstract.

One of ordinary skill in the art would have been motivated to utilize the anti-nitrotyrosine antibody in order to evaluate lung ischemia-reperfusion oxidation injury. See Ischiropoulos et al. - abstract.

II. Claims 19-22, 24-26, and 30 are rejected under 35 U.S.C.103(a) as being unpatentable over Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) and further in view of Peppard, Jane V. (Monoclonal Antibodies, 2000, pages 297-318).

Please see Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) as set forth above.

Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) differ from the instant invention in not specifically teaching the various claimed supports and labels that have utility in the instance method.

However, Peppard discloses Immunoassay procedures. Peppard further teaches that the choice of labels and solid supports are selected in order to optimize the assay procedure. In particular, see pages 301-308. Various embodiments of solid supports and labels meeting the claimed limitations are described. The labels and solid supports can be mixed and matched according to the assay requirements. See page 297 1st paragraph. Absent evidence to the contrary the selection of known solid supports and labels in the procedure taught by Robinson et al. in view of Ischiropoulos et al. is deemed mere adjustment and optimization, which is routinely conducted in immunoassay procedures to achieve the best sensitivity and precise for the analyte of interest.

Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) disclose the invention except for the various labels and solid supports recited in claims 19-22, 24-26, and 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select from the various labels and solid supports to maximize the assay detection parameters as taught by Peppard (see pages 297, 301, and 303) since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

III. Claim 23 is rejected under 35 U.S.C.103(a) as being unpatentable over Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) and further in view of Engelhardt et al. (US patent #6,221,581 B1).

Please see Robinson et al. (Analytical Biochemistry, Vol.266, pages 48-57, 1999) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) as set forth above.

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However, Engelhart et al. disclose polynucleotide probes that can be employed in solution or fixed to a solid support and matrix in order to capture reagents and subsequently allow for assay detection. These polynucleotide supports can be used to detect genetic mutations or defects in genetic material. See abstract and column 5 lines 29 though column 6 line 12.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ an nucleic acid support as taught by Engelhart et al. in the procedure of Robinson et al. in view of Ischiropoulos et al. because Engelhart et al. taught this would allow for the detection of genetic mutations or defects in genetic material. See Engelhart et al. - abstract and column 5 lines 29 though column 6 line 12.

IV. Claims 17, 18, 27, 28, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pompella et al. (Histochem Cell Biol, Vol.105, pages 173-178, 1996) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only).

Pompella et al. disclose a fluorescence microscopy method for detecting oxidative stress. See abstract. In the procedure cells were adhered to polylysine-coated glass slides and exposed to 2,4 DNPH). The carbonyls present in the protein samples were measured by an anti-dinitrophenyl antibody and an anti-rabbit Ig biotinylated antibody. See page 174 2nd column and page 175 2nd column.

Pompella et al. differ from the instant invention in not specifically teaching the utility of an anti-nitrotyrosine antibody in oxidative stress analyses.

However, Ischiropoulos et al. teach procedures to measure oxidative tissue injury associated with decreased pulmonary flow. Specifically, ischemic-reperfused lungs were used to measure the contribution or nitric oxide and peroxynitrite in tissue injury. The nitrotyrosine concentration increased in reperfused/ischemia lungs and specific binding of an anti-nitrotyrosine antibody was seen. See abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ an anti-nitrotyrosine antibody as taught by Ischiropoulos et al. in the oxidative procedure of Pompella et al. because Ischiropoulos et al. taught that nitrotyrosine concentrations increased in reperfused/ischemia lungs and specific binding of an anti-nitrotyrosine antibody was seen. See Ischiropoulos et al. - abstract.

One of ordinary skill in the art would have been motivated to utilize the anti-nitrotyrosine antibody in order to evaluate lung ischemia-reperfusion oxidation injury. See Ischiropoulos et al. - abstract.

V. Claims 19-22, 24-26, and 30 are rejected under 35 U.S.C.103(a) as being unpatentable over Pompella et al. (Histochem Cell Biol, Vol.105, pages 173-178, 1996) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) and further in view of Peppard, Jane V. (Monoclonal Antibodies, 2000, pages 297-318).

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However, Peppard discloses Immunoassay procedures. Peppard further teaches that the choice of labels and solid supports are selected in order to optimize the assay procedure. In particular, see pages 301-308. Various embodiments of solid supports and labels meeting the claimed limitations are described. The labels and solid supports can be mixed and matched according to the assay requirements. See page 297 1st paragraph. Absent evidence to the contrary the selection of known solid supports and labels in the procedure taught by Robinson et al. in view of Ischiropoulos et al. is deemed mere adjustment and optimization, which is routinely conducted in immunoassay procedures to achieve the best sensitivity and precise for the analyte of interest.

Pompella et al. (Histochem Cell Biol, Vol.105, pages 173-178, 1996) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) disclose the invention except for the various labels and solid supports recited in claims 19-22, 24-26, and 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to select from the various labels and solid supports to maximize the assay detection parameters as taught by Peppard (see pages 297, 301, and 303) since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

VI. Claim 23 is rejected under 35 U.S.C.103(a) as being unpatentable over Pompella et al. (Histochem Cell Biol, Vol.105, pages 173-178, 1996) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) and further in view of Engelhardt et al. (US patent #6,221,581 B1).

Please see Pompella et al. (Histochem Cell Biol, Vol.105, pages 173-178, 1996) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) as set forth above.

Pompella et al. (Histochem Cell Biol, Vol.105, pages 173-178, 1996) in view of Ischiropoulos et al. (American Journal of Physiology, 1995, Vol.269, No.2 13-2, pages L158-L164-Abstract Only) differ from the instant invention in not specifically teaching nucleic acid supports.

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It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ an nucleic acid support as taught by Engelhart et al. in the procedure of Pompella et al. in view of Ischiropoulos et al. because Engelhart et al. taught this would allow for the detection of genetic mutations or defects in genetic material. See Engelhart et al. - abstract and column 5 lines 29 though column 6 line 12.

9. For reasons aforementioned, no claims are allowed.

Remarks

10. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure: Maggio (Immunoenzyme technique I, CRC press © 1980, pages 186-187). disclose enzyme immunoassays wherein either the antigen or antibody is immobilized onto a solid phase. The solid phase can be particles, cellulose, polyacrylamide, agarose, discs, tubes, beads, or micro plates (micro titer plates). See page 186. The reagents can be bound to the solid support by covalent linkage or passive adsorption (non-covalent means). See page 187 1st paragraph. Maggio taught that solid supports such as test strips "are very convenient to wash thereby reducing labor in assay procedures". Page 186, last line.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Remsen 3C-59
(571) 272-0816
10/11/06

LONG V. LE 10/13/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600